

SPL Pharma Subteam -- Drug Listing/ Establishment Registration Meeting Minutes – Dec 8, 2009

Topics of discussion:

1. Michael is transitioning to a new role and has asked several people to co-chair. Eventually he will transition off the team starting in January.
2. Delisting: Meeting set up with Lonnie and Leyla for Monday 12/14 to begin discussing delisting issues and possible resolutions. Please send issues and/or comments to Michael.
 - a. Key issues:
 - i. Problem with having to submit an entire SPL file to delist the product/NDC.
 - Old products not in SPL format
 - Don't know what is in the database (ie API, OTC,)
 - b. Proposals:
 - i. Abridged SPL – similar to API-only SPL, where you include only drug data listing elements and minimal other text/data.
 - ii. Implementation period of x number of years. After that time, the previous database would be phased out/deleted. At some point, only the new database would be used.
3. Export only- no updates.
4. How is SPL / drug listing working: Issues:
 - a. OTC: where is the FDA going to publish OTC listings. They are currently not being published anywhere visible.
 - b. Customs is viewing the listing data. One company did have a problem because they hadn't previously listed the product. It was sent back by customs. After the listing was completed, the product was imported successfully. Their shipping group provided copies of the SPL listing documentation of the listing to the customs.
5. Q&A document – discussion topics.
 - a. The regulations have not changed in that paper copies of the label are still required after approval. Companies are defaulting to the specific instructions in the approval letter, which typically includes what to provide “in lieu” of paper.
 - b. Question #3 – how to submit a link in lieu of submitting SPL to both the review division and drug listing. No details have been given on how to do this.
6. Getting SPL off of Daily Med
 - a. None has had success in getting it off Daily Med
 - b. Communication bounced between Lonnie and Daily Med.
 - c. SPL had product market start and end dates on successive dates. This resulted in the product also getting put into the NDC directory.
 - d. Need 2 processes –
 - i. getting SPL off of Daily Med.
 - ii. Getting NDC codes removed from Daily Med.

7. SPL leadership and subteam meetings—
 - a. 2009 accomplishments
 - i. Brought questions and issues to FDA
 - ii. Brought awareness of SPL to new SPL users
 - b. 2010 to do:
 - i. Issues to work through: delisting, export only